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| 10/633,460 | 08/04/2003 | William J. Ayala | 2006-0191 | 4666 |

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Tampa, FL 33606

| EXAMINER | |
|---|---|
| PERREIRA, MELISSA JEAN | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/06/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/633,460 | AYALA, WILLIAM J. | |
| | Examiner | Art Unit | |
| | Melissa Perreira | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *39-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 39-60 are pending in the application. Claims 1-38 have been cancelled in the reply filed 2/2/07. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant has not provided any amendments to the specification and therefore the rejection is maintained.

### *New Ground of Rejection Necessitated by the Amendment to the Claims*

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

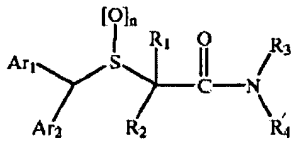
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 39-46,49,50,52-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (WO/002000/033835) in view of Bacon et al. (US 6,492,396B2) and further in view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

4. Alaux et al. (WO/2000/033835) discloses a zolpidem (nonbenzodiazepine hypnotic) or salt thereof controlled-release dosage form. The first phase or immediate phase induces the immediate sleep and is from 0-30 min while the second phase or

prolonged release is between 2-6 hours (p1, last paragraph; p2, paragraph 2 and 8). The pellet or tablet prepared from spherical granules or pellets may be incorporated into a multilayer tablet with multiple coatings with an inner layer not containing active substance, thus modulating the release profile (p3, paragraph 2 and 11; p4, paragraph 9). The formulation may contain calcium carbonate; citric acid as well as other acceptable excipients while the coating may consist of a diffusion-limiting polymer (osmotic semipermeable membrane), such as ethyl cellulose (p6, paragraph 10 and 11; p4, paragraph 4) which encompasses those of the instant claims. Alaux et al. does not disclose the use of a wakeup agent in the formulation. Also, weakening of the osmotic membrane via a seam or hole is not disclosed.

5. Bacon et al. (US 6,492,396B2) discloses a pharmaceutical composition (column 3, lines 33-34) containing a first component and a second component for treating sleep disorders and ADHD. Where the active wakeup agent (column 1, lines 53-55) of the composition is that of the structure below, modafinil where $Ar_{1-2}$ are $C_6$ aryl/phenyl (column 5, line 10; column 6, line 59) and $R_{1-4}$ are H (column 3, lines 55-60; column 6, lines 5-6; column 9, lines 54-55).




6. The pharmaceutical composition of the disclosure may include a benzodiazepine (column 35, lines 10-14 and 28) and the resulting composition may be incorporated into

fast dissolve, modified-release or sustained-release formulations that are preferable bi-modal (column 34, lines 22-26).

7. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body (column 1, lines 58-59; column 3, lines 61-64). The osmotic device is enclosed in a semi-permeable membrane that allows for a delay between the time of administration to the time of bursting while inhibiting the tendency of the active agent to leach (column 3, lines 49-55). To control this delay a thicker coating or a different material may be applied, such as cellulose acetate, cellulose nitrate or polyvinyl alcohol, as well as those listed in the instant claims (column 5, lines 32-39). Figure 2 shows the osmotic dispenser incorporating a seam or a weak spot (figure 3.) and rupturing may occur along this seam or weak spot (column 4, lines 1-35 and 47-52).

8. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole that is drilled into the capsule from the exterior to the interior and filled with active material as well as inert excipients, such as gas releasing material and is coated (claim 29, column 3, lines 1-9; 16-26 and 46-48). The drugs utilized in this device are sedatives and tranquilizers (column 4, lines 31-32). The release of the active material after it passes out of the stomach is controlled by the coating agent, such as cellulose acetate (column 6, lines 4-5).

9. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the controlled-release dosage form of Alaux et al. a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker or a drilled hole Rashid. The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active substance. It would have been obvious to one ordinarily skilled in the art to use the controlled-release dosage form of Alaux et al. for the formulation of Bacon et al. since controlled-release dosage form can be utilized with any types of pharmaceutically active substances. The treatment of a sleep disorder with a (first component) sleep promoting active substance would require that the subject obtain 8 hours of sleep to be an effective treatment and thus the formulation would need a long delay between release of the (second component) wakeup agent. One would have a great expectation of success when utilizing the tablet system of controlled-release dosage form to provide for an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time.

10. Claims 39-46,49,50-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al. (US 2003/0118648) in view of Bacon et al. (US 6,492,396B2) and further in view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

11. Hirsh et al. (US 2003/0118648) discloses of a discrete molded (compressed) controlled-release tablet comprising a first portion containing a therapeutically effective amount of a pharmaceutically active agent for intraoral administration and a second portion located around the first portion also containing a pharmaceutically active agent (p2, [0016-0017]). The composition allows for rapid release for absorption of medicament for rapid relief of symptoms followed by a delayed released manner for the second medicament (p2, [0011] and [0019]). The pharmaceutically active drugs include stimulants or hypnotics, such as zolpidem (p3, [0033]). Film coatings (p5, [0057]), excipients include ethyl cellulose p4, [0040-0041]) and effervescent agent, such as alkali bicarbonate may be included in the formulation (p5, [0059]). Hirsh et al. does not disclose the use of a wakeup agent in the formulation. Also, weakening of the osmotic membrane via a seam or hole is not disclosed.

12. Bacon et al. (US 6,492,396B2) discloses a pharmaceutical composition (column 3, lines 33-34) containing a first component and a second component for treating sleep disorders and ADHD as well as that stated above.

13. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body as well as that stated above.

14. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole that is drilled into the capsule from the exterior to the interior and filled with active material as well as inert excipients as well as that stated above.

15. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the controlled-release tablet of Hirsh et al. a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker or a drilled hole Rashid. The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active substance. It would have been obvious to one ordinarily skilled in the art to use the controlled-release tablet of Hirsh et al. for the formulation of Bacon et al. since controlled-release dosage form can be utilized with any types of pharmaceutically active substances. The treatment of a sleep disorder with a (first component) sleep promoting active substance would require that the subject obtain 8 hours of sleep to be an effective treatment and thus the formulation would need a long delay between release of the (second component) wakeup agent. One would have a great expectation of success when utilizing the tablet system of controlled-release tablet to provide for an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time.

16. Claims 39-46,49,50-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh et al. in view of Miller et al. (US 2001/0034373A1) and in further view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

17. Hirsh et al. (US 2003/0118648) discloses of a discrete molded (compressed) controlled-release tablet comprising a therapeutically effective amount of a pharmaceutically active agent for intraoral administration with a second portion located around the first portion with a pharmaceutically active agent as well as that stated above. Hirsh et al. does not disclose the use of a wakeup agent in the formulation. Also, weakening of the osmotic membrane via a seam or hole is not disclosed.

18. Miller et al. (US 2001/0034373A1) discloses a modafinil composition for improving cognitive function in a subject (p1, [0008]) that may include other pharmaceutical agents, such as benzodiazepines or fluphenazine (p2, [0014]).

19. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body as well as that stated above.

20. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole as well as that listed above.

21. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the controlled-release tablet of Hirsh et al. a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker or a drilled hole Rashid. The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active

substance. It would have been obvious to one ordinarily skilled in the art to use the controlled-release tablet of Hirsh et al. for the formulation of Miller et al. since the tablet system can be utilized with any types of pharmaceutically active substances. The method for restoring cognitive function in a subject in necessary to improve the quality of life and productivity of humans. One would have a great expectation of success when utilizing the controlled-release tablet of Hirsh et al. to provide for such an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time.

22. Claims 39-46,49,50,52-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (WO/2000/033835) in view of Miller et al. (US 2001/0034373A1) and in further view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

23. Alaux et al. (WO/2000/033835) discloses a zolpidem (nonbenzodiazepine hypnotic) or salt thereof controlled-release dosage form. The first phase or immediate phase induces the immediate sleep and is from 0-30 min while the second phase or prolonged release is between 2-6 hours as well as that stated above. Alaux et al. does not disclose the use of a wakeup agent in the formulation. Also, weakening of the osmotic membrane via a seam or hole is not disclosed.

24. Miller et al. (US 2001/0034373A1) discloses a modafinil composition for improving cognitive function in a subject (p1, [0008]) that may include other pharmaceutical agents, such as benzodiazepines or fluphenazine (p2, [0014]).

25. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body as well as that stated above.

26. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole as well as that listed above.

27. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the controlled-release dosage form of Alaux et al. a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker or a drilled hole Rashid. The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active substance. It would have been obvious to one ordinarily skilled in the art to use the controlled-release dosage form of Alaux et al. for the formulation of Miller et al. since the tablet system can be utilized with any types of pharmaceutically active substances. The method for restoring cognitive function in a subject in necessary to improve the quality of life and productivity of humans. One would have a great expectation of success when utilizing the controlled-release dosage form of Alaux et al. to provide for such an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time.

28. Claims 39-50 and 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopinet-Cote et al. (EP 1074249A1) in view of Bacon et al. (US 6,492,396B2) and in further view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

29. Chopinet-Cote et al. (EP 1074249A1) discloses a tablet system having a core-centered body covered with adjacent layers, one element fully enclosing the other. The enclosed elements have active substance while the enclosing element is devoid of active substance and delays the release of the latter by a no-release period. The enclosing element has an intrinsic porosity that will remain constant while allowing aqueous medium to penetrate and thus a rapid release of active substance (abstract; p4, [0020]). The enclosed element comes into contact with aqueous medium through the porous coating and is altered in volume due to swelling allowing for a rapid release of the core active agent (p5, [0033]). The oral delivery tablet system for pharmaceutical use is capable of releasing an active substance during a release period of predetermined duration and quantity of active agent followed by a no-release period devoid of active substance then a subsequent release period having a predetermined release rate (p2, [0003]; p4, [0019]). By controlling the amount of retarding (no-release) layer, such as cellulose acetate and others listed in the instant claims the lag time can be 3 h up to 6 or 7 h (p 19, [0124] and [0126]). The fast release layer is comprised of active substance and excipients, such as sodium hydrogen carbonate and citric acid that promote fragmentation and disintegration via effervescence (p6, [0039]). Figure 2 provides a schematic of the tablet system comprising a core with active substance, an intermediate layer devoid of active substance and an external coating layer with active

substance (p8, [0052]) while figure 3 contains those described in figure 2 and an external coating layer (p9, [0059]). The tablet system may be comprised of a plurality of couples of tablet elements (p4, [0025]). Chopinet-Cote et al. does not disclose the use of a hypnotic, tranquilizer, etc and a wakeup agent in the formulation. Also, weakening of the osmotic membrane via a seam or hole is not disclosed.

30. Bacon et al. (US 6,492,396B2) discloses a pharmaceutical composition (column 3, lines 33-34) containing a first component and a second component for treating sleep disorders and ADHD as well as that stated above. The sleep-compatible

31. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body as well as that stated above.

32. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole that is drilled into the capsule from the exterior to the interior and filled with active material as well as inert excipients as well as that stated above.

33. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the tablet systems of Chopinet-Cote et al. a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker or a drilled hole Rashid. The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active

substance. It would have been obvious to one ordinarily skilled in the art to use the tablet systems of Chopinet-Cote et al. for the formulation of Bacon et al. since the tablet system can be utilized with any types of pharmaceutically active substances. The treatment of a sleep disorder with a (first component) sleep promoting active substance would require that the subject obtain 8 hours of sleep to be an effective treatment and thus the formulation would need a long delay between release of the (second component) wakeup agent. One would have a great expectation of success when utilizing the tablet system of Chopinet-Cote et al. to provide for an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time.

34. Claims 39-50 and 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopinet-Cote et al. (EP 1074249A1) in view of Miller et al. (US 2001/0034373A1) and in further view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

35. Chopinet-Cote et al. (EP 1074249A1) discloses a tablet system having a core-centered body covered with adjacent layers, one element fully enclosing the other. The enclosed elements have active substance while the enclosing element is devoid of active substance and delays the release of the latter by a no-release period as well as that stated above. Chopinet-Cote et al. does not disclose the use of a hypnotic, tranquilizer, etc and a wakeup agent in the formulation. Also, weakening of the osmotic membrane via a seam or hole is not disclosed.

36. Miller et al. (US 2001/0034373A1) discloses a modafinil composition for improving cognitive function in a subject (p1, [0008]) that may include other pharmaceutical agents (antidepressants), such as benzodiazepines or fluphenazine (p2, [0014]).

37. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body as well as that stated above.

38. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole as well as that listed above.

39. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the tablet systems of Chopinet-Cote et al. a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker or a drilled hole Rashid. The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active substance. It would have been obvious to one ordinarily skilled in the art to use the tablet systems of Chopinet-Cote et al. for the formulation of Miller et al. since the tablet system can be utilized with any types of pharmaceutically active substances. The method for restoring cognitive function in a subject in necessary to improve the quality of life and productivity of humans. One would have a great expectation of success

when utilizing the tablet system of Chopinet-Cote et al. to provide for such an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time.

40. Claims 39-49,51-54 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (WO/2000/033835), Hirsh et al. (US 2003/0118648) or Chopinet-Cote et al. (EP 1074249A1) in view of Wiggins (US 3,443,014).

41. Alaux et al. (WO/2000/033835) discloses a zolpidem (nonbenzodiazepine hypnotic) or salt thereof controlled-release dosage form as well as that stated above.

42. Hirsh et al. (US 2003/0118648) discloses of a discrete molded (compressed) controlled-release tablet comprising a therapeutically effective amount of a pharmaceutically active agent for intraoral administration with a second portion located around the first portion with a pharmaceutically active agent as well as that stated above.

43. Chopinet-Cote et al. (EP 1074249A1) discloses a tablet system having a core-centered body covered with adjacent layers, one element fully enclosing the other. The enclosed elements have active substance while the enclosing element is devoid of active substance and delays the release of the latter by a no-release period as well as that stated above.

44. None of the disclosures of Alaux et al, Hirsh et al. or Chopinet-Cote et al. disclose the controlled release formulations with caffeine as one of the active agents.

45. Wiggins (US 3,443,014) discloses a pharmaceutical preparation containing a hypnotic, tranquilizing compound and caffeine (claims 4-7) for the method of relieving pain in a subject.

46. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use any one of the controlled-release dosage forms of Alaux et al., Hirsh et al. or Chopinet-Cote et al. for the pharmaceutical preparation of Wiggins as since the controlled-release dosage forms can be utilized with any types of pharmaceutically active substances. The method for relieving pain in a subject is necessary to improve the quality of life and productivity of humans. One would have a great expectation of success when utilizing the controlled-release dosage form of Alaux et al., Hirsh et al. or Chopinet-Cote et al. to provide for such an effective treatment as the proper amount of each pharmaceutically active substance is released at the required time. The zolpidem compound of Alaux et al. and Hirsh et al. is also a hypnotic drug which can be substituted for the hypnotic drug of Wiggins as they provide the same function.

***Conclusion***

No claims are allowed at this time.

47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

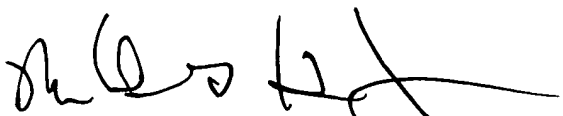
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
March 29, 2007



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER